

# Sr. Specialist, QA Compliance

Job ID  
REQ-10052687  
Jun 03, 2025  
USA

## Summary

The Senior Specialist, Quality Assurance Compliance supports the implementation of robust Quality Systems for the Durham Site of Novartis Gene Therapies, considering global regulatory and local requirements of the organization. This role contributes significantly to the execution of these systems, authors or contributes to the procedures governing these systems and works towards timely implementation, including support of Quality Management Review, ownership/execution of Self-Inspection program and in the management of health authority inspections.

Location: Durham, NC #LI-Onsite, Hybrid

## About the Role

### Key Responsibilities:

- Contributes significantly to the Readiness Program; site inspection preparation, program management, response and commitment process for health authority inspections.
- Leads site self-inspection program including preparation of risk based annual audit plan, lead auditor responsibilities, audit agendas, inspection reports and CAPA plan approvals.
- Provide strategic quality input on the design and architecture of Novartis Gene Therapies Quality Management System.
- Supports the development and oversight of robust quality systems, including both implementation and operation at site level.
- Supports management to implement and maintain the following programs: Annual Product Quality Review (APQR), Compliance Alert actions, and Novartis Global document assessments required to be performed at the site level.
- Supports supplier monitoring and oversight activities including audit responses, CAPAs, and evaluation of supplier risk levels.
- Supports the site level Quality Management Review (QMR) program including monitoring and reporting key performance indicators, as appropriate.
- Performs duties as assigned to ensure compliance with global and local regulations.
- Represent Quality Assurance Compliance team on project teams and in meetings as needed.
- Support the continuous improvement and oversight of QA Compliance programs through planning and implementation.
- Identifies and implements new technologies to improve compliance an efficiency of QS operations.
- Adheres to all GMP requirements.
- Ownership of Compliance Records relevant to quality systems responsibilities (Change Records, CAPAs, Quality Events, Deviations as needed).

## Essential Requirements:

- Bachelor's degree in Life Sciences or Chemistry (preferred) or related relevant degree with 7 years of experience in GMP manufacturing operations, Bio-Pharma or Gene therapies preferred.
- Previous experience in QA Compliance including self-inspections, health authority inspections and supplier auditing, preferably with a minimum of 2 year's of experience as a lead inspector.
- Experience reviewing systems and analyze data (paper or electronic) to identify specific compliance and data consistency issues.
- Previous Quality Assurance experience required, including Data Integrity (ALCOA+) compliance.
- Ability to apply a phase appropriate, risk-based approach to QA operational decisions.
- Experience supporting cGMP manufacturing operations through administration and enforcement of the Quality Management System.
- Proficient in cGMP/ICH/FDA/EU regulations and guidelines and experience in US and international regulatory agency inspections a plus.
- Proficient in using Microsoft applications (MS Word, MS Excel, MS PowerPoint).
- Strong follow-up and organizational skills and ability to manage cross functional projects.
- Experience with viral gene therapies and/or orphan disease indications a plus.
- Direct experience reviewing and/or authoring standard operating procedures.
- Ability to work well independently and within a team.
- Excellent oral and written communication skills with technical writing experience required.

*The salary for this position is expected to range between \$73,500 and \$136,500 per year.*

*The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.*

*Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.*

*US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.*

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Division

Operations

Business Unit

Innovative Medicines

Location

USA

State

North Carolina

Site

Durham

Company / Legal Entity

U473 (FCRS = US473) Novartis Gene Therapies

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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